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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,817	02/26/2002	George F. Schreiner	SCIOS.002C1	8504

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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,817	SCHREINER ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11/26/02 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

The current status of all nonprovisional parent applications referenced should be included in the first line of the specification. Therefore, U.S. Pat. App. No. 09/392,932 should refer to U.S. Pat. No. 6,352,975. Correction is required.

Specification

The abstract of the disclosure is objected to because it does not refer to the claimed invention (method of treating *essential* hypertension). Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed (i.e. treatment of essential hypertension, and not to compositions).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim is directed to a method of treating essential hypertension. Essential hypertension is defined in the art as elevated blood pressure wherein the cause is unknown. 90% of patients with elevated blood pressure are considered to have essential hypertension. The instant specification uses an animal model of hypertension which is a salt-sensitive following short-term exposure to angiotensin II (see Lombardi et al. Hypertension 33: 1013-1019, 1999). However, one of ordinary skill in the art at the time of the instant invention would not find the animal model which is used in the specification to be predictive of essential hypertension. Therefore, the results of treatment of salt-sensitive hypertension in the rat induced by angiotensin-II infusion would not be predictive of essential hypertension in a patient, absent evidence to the contrary. The mechanisms of hypertension vary greatly on the type of hypertension that is present. Some forms of hypertension are genetic, some are induced by endocrine disease, some are induced by tumors, some are induced by renal disease, and some are induced by drugs (see Ganong, Review of Medical Physiology, Appleton and Lange, 1989, page 543, Table 33-4). Some therapies which work for one type of hypertension will not be predictive for treatment of other forms of hypertension because the underlying causes vary. For example, reduction of salt-intake can be effective for treatment of salt-dependent hypertension, but this does not always provide an effective treatment for essential hypertension. Therefore, one of ordinary skill in the art at the time of the instant invention would not find the experimental evidence for salt-sensitive hypertension induced by angiotensin II infusion provided in the instant

specification predictive or correlative with treatment of essential hypertension, absent evidence to the contrary.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification discloses treatment of salt-sensitive hypertension by the administration of VEGF121 and VEGF165. The instant specification contemplates treatment of essential hypertension with any angiogenic factor or agonist thereof. However, the instant specification fails to provide an adequate written description for the breadth of this claim in that disclosure of VEGF121 and VEGF165 as effective for treatment of salt-sensitive hypertension is not predictive for administration of any angiogenic factor for the treatment of essential hypertension. First, the specification discloses that there are a number of known growth factors, including basic and acidic fibroblast growth factor, transforming growth factor α and epidermal growth factor which are angiogenic. However, the specification also continues to indicate that the lack of specificity of these factors my cause the proliferation of other cell types along with endothelial cells which could cause blockage and/or reduced blood flow (see page 3, paragraph 2 of the specification). Therefore, the instant specification acknowledges that the use of the these angiogenic factors may not be effective for the treatment of

hypertension. One of ordinary skill in the art would not find the disclosure adequate to support the instant claim to use of any angiogenic factor or agonist for the treatment of essential hypertension because Applicant's own disclosure indicates that the breadth of "angiogenic factor" includes factors which would not be expected to be effective for this purpose. Therefore, the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by ROF (U.S. Pat. No. 5,240,714, issued 08/31/93).

ROF teach a factor which modulates angiogenesis (see abstract). ROF also teaches a method of treating essential hypertension by the administration of an effective amount of the factor to a patient (see claim 6). Therefore, the instant claim is anticipated by the prior art of ROF.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-7519. The examiner can normally be reached on Monday through Thursday 8:00AM-2:00PM; voice mail service is available.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud